

**St. Luke's
Roosevelt**

OBESITY RESEARCH CENTER

University Hospital of
Columbia University College
of Physicians & Surgeons

212 523 4830 P.01/01

**St. Luke's-Roosevelt
Hospital Center**

St. Luke's Division
1111 Amsterdam Avenue
New York, NY 10025

July 7, 2000

VIA FACSIMILE

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852
Fax: 301-443-3100

Joseph A. Levitt, Esq.
Director, Center For Food Safety and
Applied Nutrition
Food and Drug Administration
Federal Building 8
200 C Street, S.W.
Washington, D.C. 20204
Fax: 202-205-5025

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Re: Clinical Safety Study of Dietary Supplements Containing Ephedrine Alkaloids

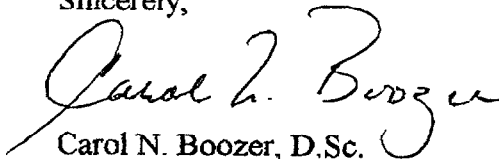
Dear Commissioner Henney and Mr. Levitt;

Dr. Daly and I understand that the FDA is interested in a study that we have been conducting on the safety of dietary supplements containing ephedrine alkaloids. As the principal investigators responsible for conducting the study, we are aware that there is significant interest in the study results and felt it might be helpful to brief you on its status.

The clinical phase of the study has been completed and the data are now being analyzed and prepared for publication in a peer reviewed scientific journal. An extremely large amount of data has been collected in this six-month randomized double blind study and we are proceeding with careful statistical analysis of multiple safety endpoints. We hope to have a draft manuscript prepared by the end of August. Of course, we do not know when the paper will be published, but we will encourage the journal to publish it as soon as possible, given the public interest in dietary supplements containing ephedrine alkaloids.

We feel that the results of this study will provide significant and important information for your agency and for consumers. For that reason, it is very important that the data go through the usual publication process of peer review. Although we are unable to provide you with substantive information concerning the results of the study at this time since the data analyses have not been completed, we will do our best to get this information into the medical literature as soon as possible.

Sincerely,


Carol N. Boozer, D.Sc.

Cc: Patricia Daly, M.D.

Continuum Health Partners, Inc.

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Beth Israel

St. Luke's
Roosevelt

Long Island
College Hospital

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